DETAILED ACTION

1. Claims 1-27 are pending. Claims 1 and 16-27 have been amended in this communication filed 03/11/08 entered as Response After Non-Final Action and Request for Extension of Time.

2. The claim objections for claims 17-27 have been overcome by Applicants' amendment to claims 17-27 and are hereby withdrawn.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

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This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-10 are rejected under 35 U.S.C. 103(a) as being unpatentable over (US 5,737,539) Edelson et al, hereafter Edelson.

With respect to claim 1, Edelson teaches, A pharmaceutical administrative system comprising: a pharmacy network including a pharmacy server and at least one pharmacy client system, the at least one pharmacy client system configured to accept and process orders for medications (col. 7, lines 16-27); and a service center network including a service center server and a service center client system, the service center network coupled to the pharmacy network and configured with a global database including a plurality of formulary records, the formulary records comprising chemical composition and properties of each of a plurality of medications (col. 7, lines 28-32), wherein the service center server supplies the pharmacy server at least one of the plurality of formulary records upon request by the at least one pharmacy client system when at least one of the orders for medication is processed (Fig.'s 6-7-show downloaded formulary information sent to a local pharmacist as part of drug order processing). Edelson did not expressly disclose "the formulary records comprising chemical composition and properties of each a plurality of medications as recited in claim 1. Nevertheless, the difference is only found in the non-functional descriptive material that does not alter the recited structural elements which remain the same regardless of the specific contents or type of records. Thus, this material will not distinguish the claimed invention from the prior art in terms of patentability, see *In re Gulak*, 703 F.2d 1381, 1385, 217 USPQ 401, 404 (Fed. Cir. 1983); *In re Lowry*, 32 F.3d 1579, 32 USPQ2d 1031 (Fed. Cir.1994): MPEP 2106. MPEP 2106.01 recites "Descriptive material can be characterized as either "functional descriptive material" or "non functional descriptive material." "Functional descriptive material" consists of data

structures and computer programs which impart functionality when employed as a computer component. (The definition of "data structure" is "a physical or logical relationship among data elements, designed to support specific data manipulation functions." The New IEEE Standard Dictionary of Electrical and Electronics Terms 308 (5th ed. 1993). "Nonfunctional descriptive material" includes but is not limited to music, literary works, and a compilation or mere arrangement of data".

With respect to claim 2, Edelson teaches, wherein the global database further includes a plurality of order records, each order record including order information for an order accepted and processed by the at least one pharmacy client system (col. 10, lines 5 - col. 11, lines 1-15).

With respect to claim 3, Edelson teaches, wherein the global database further includes a plurality of customer records, each customer record including contact and formulary information for at least one customer (col. 14, lines 53- col. 15, lines 1-6, col. 17, line 65-col. 18, line 3 –global database, col. 19, lines 45-60, and col. 22, lines 55-65).

With respect to claim 4, Edelson teaches, wherein the global database further includes a plurality of patient records, each patient record including contact information and medication history for at least one patient (col. 16, lines 10-35, col. 19, lines 1-67, and col. 20, line 50-col. 21, line 3).

With respect to claim 5, Edelson teaches, wherein the pharmacy client system is further configured to generate a medication specific label containing medication identification information (col. 26, line 56-col. 27, line 8 and col. 28, lines 21-42).

With respect to claim 6, Edelson teaches, wherein the pharmacy client system is configured to provide updates to the patient, customer, and formulary records in the global database (col. 31, lines 8-21 and lines 51-62).

With respect to claim 7, Edelson teaches, wherein updates to the formulary records include modification to the ingredients of the medication (col. 32, lines 48-59).

With respect to claim 8, Edelson teaches, wherein updates to the modification to the ingredients of the medication include changes to amounts of caloric content in the medication (col. 32, lines 54-59).

With respect to claim 9, Edelson teaches, wherein updates to the modification to the ingredients of the medication include changes to amounts and preferences of electrolytes in the medication (col. 32, lines 54-59).

This dependent claim is rejected for the similar rationale given above for claim 8.

With respect to claim 10, Edelson teaches, wherein the pharmacy client system is configured to verify the updates to the formulary records in the global database (col. 35, lines 23-33).

6. Claims 11-13 and 18 are rejected under 35 U.S.C. 103(a) as being unpatentable over (US 5,737,539) Edelson et al, hereafter Edelson in view of "On-line Medical Dictionary".

With respect to claim 11, Edelson failed to teach, wherein the medication specific label is for an intravenous solution and the medication identification information includes a refractive index associated with the intravenous solution. "Online Medical Dictionary" teaches, wherein the medication specific label is for an intravenous solution and the

medication identification information includes a refractive index associated with the intravenous solution (page 5). It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify in Edelson because such a modification would allow Edelson to have the information regarding the refractive index since the refractive index increases with the atomic number of constituent atoms in the in the intravenous solution.

With respect to claim 12, Edelson failed to teach, wherein the medication specific label is for an intravenous solution and the medication identification information includes a level of potassium associated with the intravenous solution. "Online Medical Dictionary" teaches, wherein the medication specific label is for an intravenous solution and the medication identification information includes a level of potassium associated with the intravenous solution (page 4-"ratio"-2). It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify in Edelson because such a modification would allow Edelson to use an intravenous solution for medical conditions such as dehydration to put the electrolytes back into a person's body.

With respect to claim 13, Edelson failed to teach, wherein the pharmacy client system is configured to generate a calcium phosphate solubility curve for an order accepted and processed by the at least one pharmacy client. "Online Medical Dictionary" teaches, wherein the pharmacy client system is configured to generate a calcium phosphate solubility curve for an order accepted and processed by the at least one pharmacy client (page 1). It would have been obvious to one having ordinary skill

in the art at the time the invention was made to modify in Edelson because such a modification would provide a time release of the compounds of calcium salts of phosphoric acid which are frequently used as calcium supplements.

With respect to claim 18, this dependent claim is rejected for the similar rationale as given above for claim 13.

With respect to claim 19, this dependent claim is rejected for the similar rationale given above for claim 18.

With respect to claim 20, this dependent claim is rejected for the similar rationale given above for claims 18 and 19.

Claims 11-13 and 18-20 are also considered non-functional descriptive claim language and are not accordingly given patentable weight.

Claims 14-17 are rejected under 35 U.S.C. 103(a) as being unpatentable over (US 5,737,539) Edelson et al, hereafter Edelson in view of "On-line Medical Dictionary" and further in view of (US 5,845,255) Mayaud.

With respect to claim 14, Edelson failed to teach, further comprising a backup network including a backup server, the service center server replicating records of orders for medication and providing the records replicated to the backup server, the backup server storing the records replicated in a backup database and providing access to the backup database by the pharmacy network when the service center network is not available for a predetermined amount of time. Mayaud teaches, further comprising a backup network including a backup server, the service center server replicating records of orders for medication and providing the records replicated to the backup server, the

backup server storing the records replicated in a backup database and providing access to the backup database by the pharmacy network when the service center network is not available for a predetermined amount of time (col. 17, lines 44-52, col. 46, lines 16-31, and fig. 16). It would have been obvious to one having ordinary skill in the art at the time the invention was made to incorporate the teachings of Mayaud in Edelson because such an incorporation would allow Edelson to have a server system where the file server or database management server manages the data storage over a local area network.

With respect to claim 15, Edelson failed to teach, wherein the pharmacy server is configured with a local database containing a subset of formulary records of the plurality of formulary records in the global database that specifically pertains to the pharmacy network. Mayaud teaches, wherein the pharmacy server is configured with a local database containing a subset of formulary records of the plurality of formulary records in the global database that specifically pertains to the pharmacy network (col. 1, lines 46-67, col. 2, lines 1-11, and col. 6, lines 59-64). It would have been obvious to one having ordinary skill in the art at the time the invention was made to incorporate the teachings of Mayaud in Edelson because such an incorporation would allow Edelson to have preferred drugs that vary in content and usually determinative of the cost effectiveness of a prescription in a database.

With respect to claim 16, Edelson teaches, A pharmaceutical administrative system comprising: a pharmacy network including a pharmacy server and at least one pharmacy client system, the at least one pharmacy client system configured to accept

and process orders for medications (col. 7, lines 16-27); and a service center network including a service center server and a service center client system, the service center network coupled to the pharmacy network and configured with a global database including a plurality of formulary records, the formulary records comprising chemical composition and properties of each of a plurality of medications (col. 7, lines 28-32), wherein the service center server supplies the pharmacy server at least one of the plurality of formulary records upon request by the at least one pharmacy client system when at least one of the orders for medication is processed (Fig.'s 6-7-show downloaded formulary information sent to a local pharmacist as part of drug order processing). Edelson did not expressly disclose "the formulary records comprising chemical composition and properties of each a plurality of medications as recited in claim 1. Nevertheless, the difference is only found in the non-functional descriptive material that does not alter the recited structural elements which remain the same regardless of the specific contents or type of records. Thus, this material will not distinguish the claimed invention from the prior art in terms of patentability, see *In re Gulak*, 703 F.2d 1381, 1385, 217 USPQ 401, 404 (Fed. Cir. 1983); *In re Lowry*, 32 F.3d 1579, 32 USPQ2d 1031 (Fed. Cir.1994): MPEP 2106. MPEP 2106.01 recites "Descriptive material can be characterized as either "functional descriptive material" or "non functional descriptive material." "Functional descriptive material" consists of data structures and computer programs which impart functionality when employed as a computer component. (The definition of "data structure" is "a physical or logical relationship among data elements, designed to support specific data manipulation

functions." The New IEEE Standard Dictionary of Electrical and Electronics Terms 308 (5th ed. 1993). "Nonfunctional descriptive material" includes but is not limited to music, literary works, and a compilation or mere arrangement of data". The "wherein" clause merely states the result of a limitation in the claim and is therefore given little patentable weight. See *Texas Instruments Inc. v. International Trade Commission*, 26 USPQ2d 1010 (Fed. Cir. 1993); *Griffin v. Bertina*, 62 USPQ2d 1431 (Fed. Cir. 2002); *Amazon.com Inc. v. Barnes and Noble.com Inc.*, 57USPQ2d 1747 (Fed. Cir. 2001).

wherein the pharmacy client system comprises: an order maintenance unit configured to create an order for medication for at least one customer and at least one patient (col. 35, lines 1-22); a formulary unit coupled to the order maintenance unit and presenting information about the medication to the order maintenance unit (col. 35, lines 23-55); a customer unit coupled to the order maintenance unit and presenting information relating to contact and purchasing information for the at least one customer ordering the medication; and a patient unit coupled to the order maintenance unit and the customer unit and presenting information relating to contact and medical information for the at least one patient, wherein the order maintenance unit is configured to modify the ingredients of the medication and to validate the modifications to the ingredients of the medication (col. 12, lines 42-65, col. 35, line 57-col. 36, line 57 and fig's 6-11 and 15).

With respect to claim 17, Edelson teaches, wherein the medication is an intravenous solution (col. 25, lines 46-55).

Claims 21-23 are rejected under 35 U.S.C. 103(a) as being unpatentable over (US 5,737,539) Edelson et al, hereafter Edelson and further in view of Official Notice.

With respect to claim 21, Edelson failed to teach, wherein the order maintenance unit is configured to generate medication specific labels for the medication. Official Notice is taken that it would have been obvious to one having ordinary skill in the art at the time the invention was made to have the order maintenance unit configured to generate medication specific labels for the medication to have a prescription delivery system to generate the invoice and label and other documentation prior to delivering the medication to the patient.

With respect to claim 22, Edelson failed to teach, wherein the medication specific labels for the medication includes information about a refractive index of the intravenous solution. Official Notice is taken that it would have been obvious to one having ordinary skill in the art at the time the invention was made to have the medication specific labels for the medication include information about a refractive index of the intravenous solution to have the information regarding the refractive index since the refractive index increases with the atomic number of constituent atoms in the in the intravenous solution.

With respect to claim 23, Edelson failed to teach, wherein the medication specific labels for the medication includes information about a level of potassium in the intravenous solution calculated using flame photometry. Official Notice is taken that it would have been obvious to one having ordinary skill in the art at the time the invention was made to have the medication specific labels for the medication include information

about a level of potassium in the intravenous solution calculated using flame photometry to have a major intracellular action that is widely distributed in the body in muscle tissue, nerve tissue, blood cells, and plasma which is filtered in the glomerulus, absorbed in the proximal tubule and finally excreted by exchange for sodium in the distal tubule. The reliability depends on the proper maintenance of the flame photometer and the salient features. If low serum potassium values are observed due to low intake of dietary potassium over a period of time or increased loss through kidney, vomiting or diarrhea and increased secretion of adrenal steroids or some diuretics that promote the loss of potassium a flame photometer (digital flame photometer) for simultaneous measurement is useful in these medical conditions.

9. Claims 24-27 are rejected under 35 U.S.C. 103(a) as being unpatentable over (US 5,737,539) Edelson et al, hereafter Edelson and Official Notice and further in view of (US 5,758,095) Albaum et al, hereafter Albaum.

With respect to claim 24, Edelson failed to teach, the pharmacy client system of claim 23, wherein the modifications to the ingredients of the medication includes modifications to caloric content of the medication. Albaum teaches, the pharmacy client system of claim 23, wherein the modifications to the ingredients of the medication includes modifications to caloric content of the medication (col. 10, lines 17-43). It would have been obvious to one having ordinary skill in the art at the time the invention was made to incorporate the teachings of Albaum in Edelson because such an incorporation would allow Albaum to know how many calories are in each portion of the medication and how many calories are being ingested each day especially if the patient

is on a weight loss regime or has a medical condition that requires knowing how many calories are in each portion of the medication.

With respect to claim 25, this dependent claim is rejected for the similar rationale given above for claim 24.

With respect to claim 26, Edelson failed to teach, wherein the modifications to the ingredients of the medication includes modifications to electrolytes in the medication. Official Notice is taken that it would have been obvious to one having ordinary skill in the art at the time the invention was made to have substances that dissociates into two or more ions, to some extent, in water.

With respect to claim 27, this dependent claim is rejected for the similar rationale as given above for claim 26.

Response to Arguments

Applicant's arguments filed 03/11/08 have been fully considered but they are not persuasive.

Issue no. 1: Applicants' argue: In the prior §103 rejection based on Edelson, the Examiner stated regarding claim 1 that, "Edelson failed to teach, wherein the service center server supplies the pharmacy server at least one of the plurality of formulary records upon request by a pharmacy client system when a order is processed." Office action dated December 21, 2004, page 3. In the present Office action, though, the Examiner states that this claim element reads on Edelson: "Figs. 6-7 - show downloaded formulary information sent to a local pharmacist as part of the drug

ordering processing." Office action dated September 11, 2007, page 3.

Applicant respectfully traverses this rejection. While Figs. 6 and 7 of Edelson show a screen with a column titled, "Formulary Drugs," However, Edelson's use of the word "formulary" is as a specialized term referring to a list of drugs that a medical insurance plan will pay for. Specifically, Edelson states, "As used herein, the term "drug formulary" refers to a list of preferred drugs contained in a drug benefits plan issued by a drugs benefit provider to a given patient." Edelson, column 1, lines 55-57. The difference between this specialized use of the term "formulary" in Edelson and the use of the term in the present specification and claims was discussed in the telephone interview with the Examiner in July 2005 that resulted in the removal of the original § 103 rejection based on Edelson. Nevertheless, applicants have amended claim 1 to clarify the nature of the claimed "formulary records" to specify that formulary records comprise "chemical composition and properties of each of a plurality' of medications." The clarifying nature of this amendment, as compared to a narrowing nature which it is not, is reflected by the original removal of the § 103 rejection based on Edelson in 2005-2006 without such an amendment has been considered but is not persuasive. Response: The Examiner gave the Edelson reference through review prior to making the 102 rejection and discussed the reference with other Senior Examiners in addition to changes in the Patent Laws including KSR vs Teleflex.

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Claim Construction

During examination of a patent application, pending claims are given

their broadest reasonable construction consistent with the specification. *In re Prater,* 415 F.2d 1393, 1404-05, 162 USPQ 541,550 (CCPA 1969); *In re Am. Acad. of Sci. Tech Ctr.*, 367 F.3d 1359, 1364, (Fed. Cir. 2004). Although a patent applicant is entitled to be his or her own lexicographer of patent claim terms, in exparte prosecution it must be within limits. *In re Corr,* 347 F.2d 578, 580, 146 USPQ 69, 70 (CCPA 1965). The applicant must do so by placing such definitions in the Specification with sufficient clarity to provide a person of ordinary skill in the art with clear and precise notice of the meaning that is to be construed. See also *In re Paulsen*, 30 F.3d 1475, 1480, 31 USPQ2d 1671, 1674 (Fed. Cir. 1994) (although an inventor is free to define the specific terms used to describe the invention, this must be done with reasonable clarity, deliberateness, and precision; where an inventor chooses to give terms uncommon meanings, the inventor must set out any uncommon definition in some manner within the patent disclosure so as to give one of ordinary skill in the art notice of the change).

Obviousness

A claimed invention is unpatentable if the differences between it and the prior art are "such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art." 35 U.S.C. § 103(a)(2000); *KSR Int'l v. Teleflex Inc.*, 127 S.Ct. 1727,1734, 82 USPQ2d 1385, 1391 (2007); *Graham v. John Deere Co.*, 383 U.S. 1, 13-14, 148 USPQ 459, 466 (1966).

In *Graham*, the Court held that that the obviousness analysis is bottomed on several basic factual inquiries: "[(1)] the scope and content of the prior art are to be determined; [(2)] differences between the prior art and the claims at issue are to be ascertained; and [(3)] the level of ordinary skill in the pertinent art resolved." 383 U.S. at 17, 148 USPQ at 467. See also *KSR Int'l v. Teleflex Inc.,* 127 S.Ct. at 1734, 82 USPQ2d at 1391. "The combination of familiar elements according to known methods is likely to be obvious when it does no more than yield predictable results." Id. 127 S.Ct. at 1739, 82 USPQ2d at 1395.

"When a work is available in one field of endeavor, design incentives and other market forces can prompt variations of it, either in the same field or in a different one. If a person of ordinary skill in the art can implement a predictable variation, § 103 likely bars its patentability." Id. 127 S. Ct. at 1740, USPQ2d at 1396. "For the same reason, if a technique has been used to improve one device, and a person of ordinary skill in the art would recognize that it would improve similar devices in the same way, using the technique is obvious unless its actual application is beyond his or her skill." Id.

"Under the correct analysis, any need or problem known in the field of endeavor at the time of invention and addressed by the patent can provide a reason for combining the elements in the manner claimed." 127 S. Ct. at 1742, USPQ2d at 1397.

Issue no. 2: Applicants' argue: throughout Applicants' September 7, 2004 response, the proper use of Official Notice and Applicants' objection to the use of Official Notice in the

March 4, 2004 Office Action is addressed and the Examiner's use of Official Notice in the present Office action is improper and traversed for the same reasons as set forth in detail in Applicants' September 7, 2004 have been considered but is not persuasive. Response: The Official Notice is not considered improper. The use of Official Notice can be used when something is well known. Nevertheless the Examiner will provide support for the Official Notice taken in this Office communication.

Resort can be had to (US 5,597,995) Williams et al for support for claims 21-23. Williams discloses, the order maintenance unit is configured to generate medication specific labels for the medication in col. 2, lines 3-23; wherein the medication specific labels for the medication includes information about a refractive index of the intervenous solution. The fact that the medication includes information about a refractive index of the intervenous solution is a design option. The medication labels can include information about any medication as in Williams in col. 2, lines 56-61 where the pharmacist signs off that the prescription is filled and labeled properly; and the medication specific labels for the medication includes information about a level of potassium in the intravenous solution calculated using flame photometry in col. 3, lines 43-63 where the computer displays both the doctor's original prescription image and an image of the drug product prescribed for comparison and a second computer further includes a scanner for scanning the bar code label on a given drug vial and a display for displaying the digitized image of the prescribed drug vial and a second visual comparison between the digitized image of the original medical prescription and the dispensed drug product in the specified vial before it is given to the customer. However

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the labeled drug vial can contain any formula of medication with instructions according to the doctor's prescription. In claim 26 Williams discusses the prescription order sheet consists of at least 20 fields of information which contain vial data input for the prescription and filling with information on the order sheet being that of the name of the patient, prescription number, name of the drug product, name of the doctor, and NDC code number. Nevertheless, the difference is only found in the non-functional descriptive material that does not alter the recited structural elements which remain the same regardless of the specific contents or type of records. Thus, this material will not distinguish the claimed invention from the prior art in terms of patentability, see *In re Gulak*, 703 F.2d 1381, 1385, 217 USPQ 401, 404 (Fed. Cir. 1983); *In re Lowry*, 32 F.3d 1579, 32 USPQ2d 1031 (Fed. Cir.1994): MPEP 2106. The "wherein" clauses of claims 21-23, 26, and 27 merely states the intended result of the claim limitations and is therefore given little patentable weight. See *Texas Instruments Inc. v. International Trade Commission*, 26 USPQ2d 1010 (Fed. Cir. 1993); Griffin v. Bertina, 62 USPQ 2d 1431 (Fed. Cir. 2002); *Amazon.com Inc. v. Barnesandnoble.com Inc.*, 57 USPQ2d 1747 (Fed. Cir. 2001).

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Prior art is not limited to the references being applied. Prior art includes both the specialized understanding of one of ordinary skill in the art, and common understanding of the layman. Examiners may rely on, for example, official notice, common sense, design choice, and ordinary ingenuity. See *Dann v. Johnston*, 425 U.S. 219, 189 USPQ 257 (1976) and *Leapfrog Enterprises, Inc. v. Fisher-Price, Inc.*, - -F.3d - -, 82 USPQ2d 1687 (Fed. Cir. 2007).

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Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

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A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Inquiries

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ella Colbert whose telephone number is 571-272-6741. The examiner can normally be reached on Monday, Tuesday, and Thursday, 5:30AM-3:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dixon Thomas can be reached on 571-272-6803. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Ella Colbert/
Primary Examiner, Art Unit 3696

June 8, 2008